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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,264	11/21/2003	Andre Jestin	042049-0105	8938

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EXAMINER	
SALIMI, ALI REZA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,264	JESTIN ET AL.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-28* is/are pending in the application.

4a) Of the above claim(s) *3-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed 7/14/2005. Claims 1-2 have been canceled. Claims 17-28 have been added. Claims 3-28 are pending. Claims 3-16 are directed to non-elected groups and have been withdrawn on grounds as previously stated in the Office Action mailed 1/14/05. Claims **17-28** are considered.

Applicants are reminded to cancel the claims to the non elected Group(s).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Please note any ground of rejection that has not been repeated is removed.

Claim Rejections - 35 USC § 102

Claims 17, 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Allan et al (US Patent No. 6,368,601 B1) for essentially the same reasons advanced in the previous Office Action mailed 1/31/2005. Applicants argue that ,601 patent fails to disclose an enabling disclosure. Applicant's argument as part of Paper filed 7/14/05 has been considered fully, but they are not persuasive. Allan et al disclosed the ORFs 1-13 of circovirus type II (see claim 9). This is suppose to be the entire virus, where it can be reasonably inferred comprises the ORF2 and thus composition of claim 17. Moreover, Applicants are directed to In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CA FC 2002) wherein the Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference

are nonetheless inherent in it." Applicants do not provide any argument that product taught and claimed by the ,601 patent does not inherently read on their claimed invention. The rejection is maintained.

Claims 17, 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Allan et al (US Patent No. 6,660,272 B2) for essentially the same reasons advanced in the previous Office Action mailed 1/31/2005. Applicants argue that ,272 patent fails to disclose an enabling disclosure. Applicant's argument as part of Paper filed 7/14/05 has been considered fully, but they are not persuasive. Claims 1, 2, 12, 18 of ,272 are directed to the entire circovirus type II which reads on the broad claim 17. The teaching and claims of the above cited patent meets the broad recitation of the claims. Additionally, the patent is presumed valid, the validity or lack thereof of US Patent should be challenged in the court of law, and not before the examiner. The rejection is maintained.

NEW GROUNDS OF REJECTION:

Claim Rejections - 35 USC § 112

Claims 17-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17, 20 23, and 26 are vague, indefinite and unclear for recitation of at least 90% identity or 95% identity. The claims have been interpreted in view of the specification and it not

clear what sequences are encompassed that are at least have 90% or 95% identity. Identity, homology or sequence similarity can be calculated by a variety of different methods, whereby the calculated identity between two sequences will be quite different depending on the algorithm used for calculation. Applicant has referred to various % identities, but there are no indications of the utilized algorithm to calculate the identity sequences. Furthermore, the calculation of Aidentity is affected by variables such as the relative weight given to the sequence gaps versus mismatches, or whether conservative substitutions are weighted differently from non-conservative substitutions. Since no art-recognized convention exists regarding the calculation of percent identity, the claims are vague and indefinite. This affects the dependent claims.

Claim 28 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC ∋ 112

Claims 17-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for induction of antibody response utilizing SEQ ID NO: 15 (emphasis added), does not reasonably provide enablement for inducing a protective response (vaccine). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The scope of the claims read on a vaccine development. Applicants are reminded that the field of vaccine development is considered to be highly unpredictable. According to the

specification and the state of the art the currently claimed virus attacks the immune system and disables the immune response. A vaccine is considered to be protective wherein upon re-introduction of the disease would be able to induce a long lasting protective response against a challenge. The current specification does not teach nor enables a vaccine to induce a protective response wherein upon introduction of the specific antigens or fragments thereof in to a host a protective response can be inferred. Absent teaching by the specification it would require undue experimentation for one ordinary skill in the art to enable the scope of the claims. The specification provides no teaching as to the induction of immunogenic protective response against the claimed antigenic fragments. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the invention. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).*

Claim Rejections - 35 USC ∋ 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 19-21, 23, 25, 26-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant disclosure, the applicants have only disclosed the sequences identified as SEQ ID NO: 15. No other sequences having percent identity of 90% or 95% were disclosed. Moreover, Applicants were not in possession of the entire virus comprising SEQ ID NO: 15. There is no information in the specification that indicates Applicants were in **possession** of the claimed sequences. In addition, there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed homologous regions or where the region, fragments may encompass. Therefore, a written description of the all other claimed sequences of Circovirus type B should be disclosed to overcome this rejection. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question,

the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 19 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

The following is not a prior art, but is cited as of interest to the Applicants only.

Please see priority date, the claims and SEQ ID NO: 1.

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No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi
8/3/2005

ALI R. SALIMI
PRIMARY EXAMINER